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EC DECLARATION OF CONFORMITY

Document Number: VR4390001

Manufacturer:	**Becton, Dickinson and Company** Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP, United Kingdom
Authorized Representative:	Becton Dickinson Ireland Limited. Donore Road Drogheda Co. Louth A92 YW26 Ireland
Manufacturing Site(s):	**Becton, Dickinson and Company** Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP, United Kingdom
Products:	**Catalogue number** — **Device name** 360210 — BD Vacutainer® PrecisionGlide™ Multiple Sample Needle 360211 — BD Vacutainer® PrecisionGlide™ Multiple Sample Needle 360212 — BD Vacutainer® PrecisionGlide™ Multiple Sample Needle 360213 — BD Vacutainer® PrecisionGlide™ Multiple Sample Needle 360214 — BD Vacutainer® PrecisionGlide™ Multiple Sample Needle 360215 — BD Vacutainer® PrecisionGlide™ Multiple Sample Needle
Classification:	Class IIa
Conformity Assessment Route:	Conformity is established through application of the procedures described in Annex V and Annex VII of the European Medical Devices Directive 93/42/EEC.
GMDN:	35209 – Blood collection needle basic
Notified Body:	BSI Group The Netherlands B.V Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands
CE Certificate Number:	00362
Date of issue of original CE Certificate:	22 December 1994

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. All supporting documentation is retained under the premises of the manufacturer.

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List of Harmonised Standards:

EN ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes **EN 556-1:2001** Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' **EN ISO 14971:2019** Medical devices – Application of risk management to medical devices **EN ISO 11137-1:2015 AMD 2019** Sterilization of healthcare products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices **EN ISO 11137-2:2015** Sterilization of healthcare products – Radiation – Part 2: Establishing the sterilization dose **BS EN ISO 11737-2:2020** Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process **EN ISO 10993-1:2018** Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process **EN ISO 10993-3:2014** Tests for genotoxicity, carcinogenicity and reproductive toxicity **EN ISO 10993-5:2009** Tests for in vitro cytotoxicity **EN ISO 10993-6:2016** Tests for local effects after implantation **EN ISO 10993-11:2017** Tests for systemic toxicity **EN ISO 10993-12:2012** Sample preparation and reference materials **EN ISO 10993-13:2010** Biological evaluation of medical devices Part 13: Identification and quantification of degradation products from polymeric medical devices **EN ISO 10993-15:2009** Biological evaluation of medical devices Part 15: Identification and quantification of degradation products from metals and alloys **EN ISO 10993-17:2009** Biological evaluation of medical devices Part 17: Establishment of allowable limits for leachable substances **EN ISO 10993-18:2009** Biological evaluation of medical devices Part 18: Chemical characterization of materials **EN ISO 11607-1:2009** Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems **EN ISO 11607-2:2006** Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006) **EN ISO 22442-3:2007** Medical devices utilizing animal tissues and their derivatives: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents **EN 1041:2008 + A1:2013** Information supplied by the manufacturer with medical devices **EN ISO 15223-1:2016** Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements

List of Non-Harmonised Standards:

EN ISO 6009:2016 Hypodermic needles for single use – Colour coding for identification **ISO 14001:2015** Environmental management systems - Requirements with guidance for use **EN ISO 9626:2016** Stainless steel needle tubing for the manufacture of medical devices **ISO 2859-1:1999** Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection **EN ISO 14644-1:2015** Cleanrooms and Associated Controlled Environments - Part 1: Classification of Air Cleanliness **EN ISO 14644-2:2015** Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration **EN 17141:2020** Cleanrooms and associated control environments - Biocontamination control. **IEC 62366-1 Edition 1.1 2020-06** Medical devices Part 1: Application of usability engineering to medical devices - CORR: January 31, 2016 **EN ISO 10993-2:2006** Animal Welfare Requirements **EN ISO 10993-10:2021** Tests for irritation and skin sensitization **EN ISO 10993-4:2017** Selection of tests for interactions with blood **EN ISO 22442-1:2015** Medical devices utilizing animal tissues and their derivatives: Application of risk management **EN ISO 22442-2:2015** Medical devices utilizing animal tissues and their derivatives: Controls on sourcing, collection and handling **EN ISO 11137-3:2017** Sterilisation of health care products – Radiation – part 3: Guidance on dosimetric aspects of development, validation and routine control **EN ISO 11737-1:2018 AMD 2021** Sterilization of medical devices – Microbial methods- Part 1 : Determination of a population of microorganisms on products

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SIGNED FOR AND ON BEHALF OF: Becton, Dickinson and Company

DATE OF ISSUE: 20-Dec-2022

DocuSigned by:
Anne Zavertnik
Signer Name: Anne Zavertnik
Signing Reason: I approve this document
Signing Time: 20-Dec-2022 | 10:39:25 PM GMT
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Signature: _____

Anne Zavertnik

Vice President, Regulatory Affairs

Integrated Diagnostic Systems

Document Number: VR4390001

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VERSION HISTORY

Current Version Prepared By: Matthew Tennen

REV.	Version Description
A	Transferred from QDMS to ECC – Version number remained
B	Transfer into new IVD Declaration of Conformity Template (MED-RA-001D)
C	Update to harmonised and non-harmonised standards list
D	Update to harmonised and non-harmonised standards list
E	Update to harmonised and non-harmonised standards list. Removal of India specific catalogue numbers 365073 and 365075 that were never manufactured.
F	Update harmonised EN ISO 11737-1:2006 to non-harmonised EN ISO 11737-1:2018 as per CAPA 325553.
G	Added Authorized Rep: BD Switzerland; updated EN ISO 13485-2012 to 2016; updated authorized signature to Kay Taylor.
H	Update Standards: EN ISO 10993- (parts 1 (2018),6(2016),11(2017)) to current revision, update EN ISO 11137-1: 2015 and EN ISO 11137-2:2015. Confirm all standards are aligned to the TF VS4390001.
I	Updated following as per BDVS-2020-04-29-113451: EN ISO 11737-2:2009 to BS EN ISO 11737-2:2020
J	• Corrected standard reference for EN 1041 to EN 1041:2008 + A1:2013 per IDSQUALITYPLAN7718 • Removed reference to EN ISO 14698-1 and EN ISO 14698-2 and replaced with EN 17141:2020 • Update ref to EN ISO 11137-1:2015 to EN ISO 11137-1:2015 AMD 2019 and update ref to EN ISO 11737-1:2018 to EN ISO 11737-1:2018 AMD 2021 per BDVS-2021-12-17-102739
K	• Updated Standards to current revision: EN ISO 14971:2012 to EN ISO 14971:2019 per IDSQUALITYPLAN7591and EN 62366-1 to IEC 62366-1 Edition 1.1 2020-06 per IDSQUALITYPLAN7774 • Changed European Authorized Representative from BD Switzerland to BD Ireland. Change to the EU Authorized Representative name and address due to dissolution of the Swiss-EU mutual recognition agreement. BSI Regulatory Statement accepting the appointment of BD Ireland as the EAR, dated 14 January 2022.
L	• Updated Authorised representative details from Ltd. To Limited. • Updated reference ISO 10993-10:2013 to ISO 10993-10:2021 per BDVS-2022-06-23-14310